
Musculoskeletal

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Background
Transcutaneous electrical nerve stimulation (TENS) is a non-pharmacological treatment for control of pain. It has come under much scrutiny lately with the Center for Medicare Services rendering a recent decision stating that "TENS is not reasonable and necessary for the treatment of CLBP chronic low back pain".

When reading and analyzing the existing literature for which systematic reviews show that TENS is inconclusive or ineffective, it is clear that a number of variables related to TENS application have not been considered.

While many of the trials were designed with the highest of standards, recent evidence suggests that factors related to TENS application need to be considered in an assessment of efficacy. These factors include, dosing of TENS, negative interactions with long-term opioid use, the population and outcome assessed, timing of outcome measurement and comparison groups.

Objective
The purpose of this perspective is to highlight and interpret recent evidence to help improve the design of clinical trials and the efficacy of TENS in the clinical setting.

Tested products

Study design & methods

Results

FACTORs AFFECTING TENS EFFICACY

Dosing of TENS
• Stimulation amplitude must be of sufficient strength to produce an analgesic response - strong but comfortable intensity, just below pain threshold, and continue to increase intensity as tolerated.

Stimulation frequency
• Different frequencies of stimulation activate different mechanisms.
• Because repeated TENS can produce analgesic tolerance, mixed frequency TENS may be a better choice.

Long-term usage
• Long-term usage of TENS (over months or years) is common with people buying and using TENS units for months or years, particularly for chronic pain conditions.
• The majority of controlled clinical trials examine TENS efficacy with a single treatment or up to a few weeks of treatment.
• Long-term efficacy should not be confused with long-term follow-up where patients have not used the TENS unit for months prior to evaluation.

Interactions with pharmacological agents
• Transcutaneous electrical nerve stimulation produces its effects through activation of opioid receptors in the central nervous system.
• Low-frequency TENS (1–10 Hz) activates mu-opioid receptors, and high-frequency TENS (50–150 Hz) activates delta-opioid receptors. Clinically available opioid analgesics use mu-opioid receptors to produce their effects. If opioid tolerance is present, it would follow that low frequency TENS would be ineffective and high-frequency TENS would still work. This has been confirmed in animal studies and a clinical study on patients with opioid tolerance.

Patient population
• TENS may not be effective for all pain conditions.
• TENS works by increasing endogenous inhibition and reducing central excitability. Both loss of inhibition and increased central excitability are key components in most chronic pain conditions.

FACTORS RELATED TO OUTCOME ASSESSMENT

Timing of Outcome Measurement
• As with any intervention, measurement of outcomes should occur during peak effect.
• The authors suggest that the effects of TENS should be examined while the TENS unit is activated and after a designated period of use.
• Effects of long-term usage of TENS should be examined.
• Measurement of pain intensity prior to TENS at each follow-up visit examines for cumulative effects.

Outcomes measured
• Understanding the most important outcome measures used to examine TENS efficacy will improve its use and clinical effectiveness.
• Although TENS may have an effect on resting pain in some populations, it appears to be more effective for reducing pain during movement and hyperalgesia.
• Multiple outcome measures related to patient improvement should be assessed, including effects on
medication usage, health care usage, function, and quality of life.

- To facilitate future systematic reviews, it would be helpful if standardized outcomes were adopted so that meta-analysis could be performed.

**FACTORS RELATED TO TRIAL DESIGN**

- TENS often is utilized daily for long periods and should be given to patients to use in their home environment.
- TENS should not be given as a “stand-alone” treatment but rather be evaluated as an adjunct to an ongoing stable treatment plan.
- Use of an adequate placebo is critical to all pharmacological and nonpharmacological clinical trials on pain. Therefore, all TENS clinical trials should be done using a placebo TENS unit.
- The authors also recommend comparison with a standard care group and that TENS be given in addition to standard care treatments - to determine whether the addition of TENS to standard care has an effect beyond standard care alone.

**Conclusion**

The authors suggest that future clinical trials be designed taking into account adequate dosing of TENS, medication usage, timing of outcome measurements, outcomes measured, and the clinical population to be studied.

Using the physiologic principles and basic science evidence on TENS mechanisms and time-effect profiles, along with the clinical evidence on dosing and outcomes, is imperative for future clinical design to adequately examine efficacy of TENS.

These principles also are critically important when analyzing the existing literature in systematic reviews.

**Key message**

It is important that factors related to TENS application be understood and considered in an assessment of efficacy.